IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

TURCHETTA *et al.* Atty. Ref.: 622-95; Confirmation No. 4021

Appl. No. 10/580,173 TC/A.U. 1625

Filed: May 22, 2006 Examiner: Morris, Patricia L.

For: POLYMORPHS OF 1-CYCLOPROPYL-7-(S,S)-2,8-DIAZABICYCLO[4.3.0]NON-8-YL)-6-FLUORO-1,4-DIHYDRO-8-METHOXY-4-OXO-3-QUINOLINE CARBOXYLIC ACID HYDROCHLORIDE AND METHODS FOR THE PREPARATION THEREOF

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION

I, Stefano Turchetta, hereby declare and state that:

1. I am an Italian citizen residing in Rome, Italy, and I am familiar with the English language.

2. I am a co-inventor of the present application.

3. In 1985, I graduated in Chemistry at the University "La Sapienza" of Rome, Italy and, in 1991, I obtained a PhD in Chemistry at the same University.

4. From 1990 to 2000, I worked at RECORDATI S.p.A. in Campoverde (Latina), Italy as Head Team of R&D in the field of chemical research.

5. Since 2000, I have been working at Chemi S.p.A in Patrica (Frosinone), Italy as R&D Manager.

6. I am a co-inventor of the following US patents: US 5,756,737; US 6,583,287; US 6,897,339; US 7,105,681; US 7,241,805;US 7,332,603; US 7,358,399; and US 7,417,149.

7. I am a co-author of the following scientific publications:

A. Gambacorta, M. Botta, S. Turchetta, *Tetrahedron*, 44 (15), 4837 (1988);

A. Gambacorta, S. Turchetta, M. Botta, *Synth. Commun.*, 19 (13-14), 2441 (1989);

A. Gambacorta, S. Turchetta, P. Bovicelli, M. Botta, *Tetrahedron*, 47, (43), 9097 (1991);

A. Gambacorta, S. Turchetta, S. Stefanelli, M. Botta, *Tetrahedron Lett.*, 32 (46), 6805 (1991).

8. Compression tests have been carried out on the claimed principle, either by myself or under my direct supervision and control.

9. The details of the tests and the results are set forth in the attached Report marked as Exhibit 1.

10. In the first pressure test, the active compound in pure form was pressed into a tablet, and in the second test, the active compound was mixed with the same excipients as described in Example 6 of the present application and then pressed into a tablet.

11. The results of the first and second pressure tests demonstrate that the new form A of the present invention retains its specific and characterizing crystalline form after compression.

12. Comparative solubility tests as between the crystalline moxifloxacin hydrochloride form A of the present invention and the monohydrate moxifloxacin hydrochloride disclosed in US 5,849,752 to Grunenberg have been performed either by myself or under my direct supervision and control.

13. The details of the tests and the results are set forth in the attached Report marked as Exhibit 2.

14. The results of the comparative solubility tests demonstrate that the crystalline moxifloxacin hydrochloride form A of the present invention is more soluble than the monohydrate moxifloxacin hydrochloride of Grunenberg.

I declare that all statements herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Stefano Turchetta

July 2nd 2009
Date

Attachments: Exhibits 1 & 2